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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,440	06/23/2000	Wilfried Fischer	2727-110	9975

20999 7590 06/09/2003

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/09/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,440

Applicant(s)

FISCHER ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2003 (paper no. 17).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time (1 month) and the Response, both filed 03/28/03 is acknowledged.

Claims 1-10 are pending. No amendments have been made. Claims 1-10 remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffmann et al. (US Pat. No. 5, 538,736).

Hoffmann teaches an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties, wherein the active substance-containing plaster can also contain further additives, such as plasticizers (see reference column 1, lines 20-44), (column 3, lines 17-40); (column 5, lines 1-35); (column 8, lines 11-16, 25-57). The active-substance containing plaster contains a back side, a skin side with a back layer, an active substance reservoir which can contain one or more active substances, a contact adhesive device on the skin side and optionally a detachable cover layer, wherein the part of the active substance reservoir part that remains on the skin, has better adhesion to the skin than the back layer (abstract). Hoffmann teaches that apart from the basic materials, the plaster can also contain further suitable additives, such as solubilizers, softeners, plasticizers, tackifiers, stabilizers, fillers and enhancers (col. 8, lines 11-16). The plaster can be used as a transdermal therapeutic system for the controlled administration of medical active substances or also cosmetically active substances to human or animal skin (col. 1, lines 32-43). Figure 1 demonstrates a two-part adhesive active substance-containing reservoir wherein the adhesion of the first active substance reservoir part to the skin must be greater than the adhesion between the peel-off layer and the back layer (col. 4, lines 50-67 through col. 5, lines 1-9). The back layer can be permeable or impermeable and suitable materials for the production thereof are for example, polymeric substances, such as polyethylene and

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polypropylene. Permeable back layers are, for example, textile fabrics, such as non-woven fabrics, and the like (col. 8, lines 25-38). The detachable protective layer can be made detachable by applying a silicone layer. Other detachable protective layers are for example, polyvinylchloride, treated paper cellophane, etc. (col. 8, lines 45-53).

Hoffmann teaches an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties. Hoffman is deficient only in the sense that he does not teach that the layer of adhesive is specifically rendered flowable by the addition of a plasticizer. However, Hoffmann does teach a plaster comprising two different adhesives, each with distinct adhesion properties and in addition teaches that suitable additives, such as plasticizers can also be contained in the plaster (col. 8, lines 11-16). Since the prior art teaches the use of plasticizers in the active substance-containing plaster, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include various suitable additives, particularly plasticizers, because they may serve to affect the bonding or flow properties of adhesion. The expected result would be an active substance-containing plaster for the release of medically active or cosmetically active substances to human or animal skin having distinct or different flowable adhesion properties as similarly desired by the applicant.

Response to Arguments

Applicant's arguments filed 03/28/03 have been fully considered but they are not persuasive.

Firstly, the applicant argued, "Hoffman does not teach, suggest, disclose or motivate a skilled artisan to practice the instantly claimed invention. The plaster in Hoffman has two different reservoirs for the active ingredient, and each of the reservoirs adheres differently to human skin."

This argument has been fully considered, but was not found to be persuasive. Hoffman teaches an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties. Hoffman recognizes the inclusion of plasticizers and additional suitable additives in the plaster. The plaster may also contain different active substances or active substance combinations. Hoffman discloses, according to figure 1, that the adhesion of the first active substance reservoir part to the skin must be greater than the peel-off layer and the back layer. Additionally, it is possible to bring about a gradual decrease of the active substance release to the skin. In response to applicant's argument that Hoffman does not teach a core of adhesive, which is rendered flowable by a plasticizing additive, it is noted that, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the

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claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The prior art teaches a plaster comprising the same ingredients with a similar purpose as that instantly claimed. The instant claims further, do not require the use of two distinct adhesive materials, merely because the adhesives have different bonding properties.

Secondly, the applicant argued, “nowhere in Hoffman is cold flow addressed and one skilled in the art would not expect that a ring with reduced flowability would act as a barrier for a more flexible adhesive in a core.”

This argument has been fully considered, but was not found to be persuasive. Hoffmann teaches a plaster comprising two different adhesives, each with distinct adhesion properties, wherein plasticizers are included in the plaster that can serve to affect the bonding or flow properties of adhesion. Hoffman also teaches that it is possible to bring about a gradual decrease of the active substance release to the skin. Furthermore, it is noted that the rejection was an obviousness-type rejections and not an anticipation rejection, wherein each element must be disclosed. The prior art teaches a similar formulation comprising similar ingredients for a related purpose as instantly claimed.

Lastly, the applicant argued, “One of the advantages of the instant invention is that since the ring prevents the more flowable adhesive of the core from escaping, the

flowability of the core adhesive can be increased. This would result in the core adhering with greater force to the skin, thereby facilitating the flux of the active ingredient. Nowhere in Hoffman is such an advantage contemplated."

This argument has been fully considered, but was not found to be persuasive. In response to applicant's argument that nowhere in Hoffman is such an advantage of the flowability of the core adhesive increasing contemplated, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Hoffman teaches two distinct adhesives, each with distinct adhesion properties, wherein plasticizers are included in the plaster. The adhesion of the first active substance reservoir part to the skin is greater than the adhesion between the peel off layer and the back layer. Additionally, the plaster of Hoffman can have adhesive areas that can contain non-adhesive areas for improved active substance permeability. There is no significant difference observed between the instant invention and the prior art since plaster of Hoffman comprises the same ingredients in a similar formulation to that of the instant invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

June 04, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600